

---

IN RE: REZULIN LITIGATION

: SUPERIOR COURT OF NEW :  
:JERSEY  
: LAW DIVISION  
: MIDDLESEX COUNTY  
:  
: CIVIL ACTION  
:  
: CASE CODE 246  
:  
:

---

PLAINTIFFS' FIRST DEMAND FOR PRODUCTION  
OF DOCUMENTS BY CATEGORY

General Instructions

Plaintiffs serve Demand For Production of Documents upon defendants, Warner-Lambert Company; Parke-Davis; and Pfizer, Inc. pursuant to the New Jersey Rules of Court. **Defendants must, with respect to each requested item or category, “organize and label them to correspond with the categories in the request,” pursuant to the strict requirements set forth in Rule 4:18-1.** Should there be a different answer to an interrogatory question depending upon which defendant is answering the question, please so indicate clearly so that the identity of each defendant appears before each answer.

### INSTRUCTIONS:

1. The term “you” or “your” or “defendants” shall mean Warner-Lambert Company; Parke-Davis; and Pfizer, Inc., and all of their predecessors, subsidiaries, divisions, affiliates and agents and employees.
2. “Rezulin” shall mean any product sold under the brand name Rezulin and/or its generic or chemical name, Troglitazone.
3. When asked to identify a communication, or if an answer involves a communication, for each communication please state the parties to the communication, the nature of the communication (*e.g.* written, oral, recorded), witnesses to the communication, and the substance of the communication.
4. When asked to identify a document, or when an answer involves a document, please state the person who wrote, composed or created the document, the intended recipients, the date originated, the date sent, the date received, all persons having copies of the document, and the subject matter and content. In lieu of identifying a document, a copy of the document can be attached to these responses.
5. Each Demand for Production of Documents set forth herein refers to information in the custody, control and possession of any defendant or known to any defendant, as well as in the custody, control and possession of or known to defendants’ counsel, representatives, agents, servants, investigators and consultants, and their counsel, employees, representatives, agents, servants, investigators and consultants.
6. If there is a claim of privilege with respect to any response, please provide a privilege log which states the nature of the information being withheld, the general subject matter of the withheld information, a statement of the facts constituting the basis for any claim of privilege, and the specific basis on which the privilege is claimed.
7. The term “person” is used in its broadest possible sense and includes a natural person, corporation, time, association, organization, business, trust, corporation, governmental or other public entity.
8. When asked to identify a person, or if the response involves a person, for each person please state the full name, business title, and the last known home and business addresses and telephone numbers.

Plaintiffs hereby demand that defendants produce the following documents:

1. All documents relating to **United States v. Warner Lambert** (1995)
2. All documents, correspondence, email, communications, consulting agreements, and retainer agreements, between Warner-Lambert and its employees, and the **National Institutes of Health (NIH)** and its employees, and the **NIH Diabetes Prevention Program**.
3. All documents, correspondence, email, communications, consulting agreements, and retainer agreements, between Warner-Lambert and its employees, and the **American Society of Endocrinology** and its employees.
4. All documents, correspondence, email, communications, consulting agreements, and retainer agreements, between Warner-Lambert and its employees, and the **Endocrinologic and Metabolic Drugs Advisory Committee**.
5. All documents, correspondence, email, communications, consulting agreements, retainer agreements, and lobbying agreements between Warner-Lambert and its employees, and the **American Diabetes Association, National Diabetes Education Initiative, or any other diabetes support, research, or advocacy organization**.

6. All documents, correspondence, email, communications, consulting agreements, and retainer agreements, between Warner-Lambert and its employees, and the **Food and Drug Administration**.

a) All communications between Warner-Lambert and the following individuals:

- i) John **Guerigian**
- ii) Robert **Misbin**
- iii) Alexander **Fleming**
- iv) Robert **Graham**
- v) Mac **Lumpkin**
- vi) Janet **Woodcock**

7. All **timelines** created by or for Warner-Lambert, which describe the schedule research, development, testing, approval, and/or marketing of Rezulin.

8. All **financial projections** and reports created by or for Warner-Lambert for Rezulin

9. All **Annual Reports** and any filings submitted to the Securities and Exchange Commission by or for Warner-Lambert for the years 1985 – 2000.

10. All **promotional information, brochures, or point of purchase displays**, provided by Warner-Lambert to physicians, hospitals, or any health care providers relating to Rezulin; and all print, radio, and television **advertising** directed at consumers, promoting or relating to Rezulin.

11. All **information provided to shareholders** by Warner-Lambert relating to Rezulin.

12. All correspondence and information provided by Warner-Lambert to physicians and health care practitioners (including, but not limited to “**Dear Doctor**” letters) relating to Rezulin.

13. All **Rezulin Regulatory Files**, including, but not limited to:

- a) The **Rezulin Investigational New Drug files** (IND); and
- b) The **Rezulin IND Contact files**; and
- c) The **Rezulin New Drug Application** (NDA); and
- d) The **Rezulin NDA Contact files**; and
- e) **Drug Safety Submissions**, including, but not limited to Drug Experience Reports, Med Watch Reports, and Periodic Adverse Drug Experience Reports

14. All documents relating to the **Phase I studies** for Rezulin.

15. All documents relating to the **Phase II studies** for Rezulin.

16. All documents relating to the **Phase III studies** for Rezulin.

17. All documents relating to the **Phase IV studies** for Rezulin.

18. All clinical trial data for Rezulin, including, but not limited to the following :

- a) Each and every **laboratory notebook**, which includes any information regarding the testing, safety, efficacy, or regulatory approval of Rezulin.
- b) All patient data on **patients who remained** in the studies.
- c) All patient data on **patients who did not remain** in the studies.
- d) Each and every **echocardiogram** on every patient.
- e) All documentation relative to **drug interaction**.
- f) All documentation relative to **liver toxicity and elevated liver enzymes**.
- g) All documentation relative to **cardiac toxicity**.
- h) All documentation relative to the propensity of Rezulin to cause **weight gain**
- h) All **Adverse Drug Event (ADE)** reports on Rezulin

19. All **documents which Warner-Lambert produced to the FDA** relating to Rezulin, including but not limited to **NDA, IND, and ANDA**.

20. All **agreements relating to Rezulin** entered into between Warner-Lambert, Sankyo, Glaxo, Parke Davis, Pfizer, or with any of their subsidiaries or divisions.

21. All documents, agreements, financial records, and work product arising out of any relationship between Warner-Lambert and any **promotional firm, public relations firm, advertising agency, communications firm, publicist, or lobbyist** (including, but not limited to Ketchum Communications, and Klemptner Advertising), which relationship involved in whole or in part, the product, Rezulin.

22. All documents and financial records relating to or evidencing the following:

- a) **Payments** made by or on behalf of Warner-Lambert to employees or personnel of the NIH, FDA, Congressmen, Senators, diabetes support, education, research, or advocacy organizations, physicians, or persons engaged in drug trials, testing, or regulatory approval of Rezulin.
- b) **Gifts** given by or on behalf of Warner-Lambert to employees or personnel of the NIH, FDA, Congressmen, Senators, diabetes support, education, research, or advocacy organizations, physicians, or persons engaged in drug trials, testing, or regulatory approval of Rezulin.
- c) **Travel** expenses paid for by or on behalf of Warner-Lambert to, or for the benefit of employees or personnel of the NIH, FDA, Congressmen, Senators, diabetes support, education, research, or advocacy organizations, physicians, or persons engaged in drug trials, testing, or regulatory approval of Rezulin.
- d) **Seminar** expenses paid for by or on behalf of Warner-Lambert to, or for the benefit of employees or personnel of the NIH, FDA, Congressmen, Senators, diabetes support, education, research, or advocacy organizations, physicians, or persons engaged in drug trials, testing, or regulatory approval of Rezulin.
- e) **Entertainment** expenses paid by or on behalf of Warner-Lambert to, or for the benefit of employees or personnel of the NIH, FDA, Congressmen, Senators, diabetes support, education, research, or advocacy organizations, physicians, or persons engaged in drug trials, testing, or regulatory approval of Rezulin.
- f) **Donations** made by or on behalf of Warner-Lambert to, or for the benefit of employees or personnel of the NIH, FDA, Congressmen, Senators, diabetes support, education, research, or advocacy organizations, physicians, or persons engaged in drug trials, testing, or regulatory approval of Rezulin.
- g) **Consulting fees** paid by or on behalf of Warner-Lambert to, or for the benefit of employees or personnel of the NIH, FDA, Congressmen, Senators, diabetes support, education, research, or advocacy organizations, physicians, or persons engaged in drug trials, testing, or regulatory approval of Rezulin.
- h) **Research grants** paid by or on behalf of Warner-Lambert to, or for the benefit of employees or personnel of the NIH, FDA, Congressmen, Senators, diabetes support, education, research, or advocacy organizations, physicians, or persons engaged in drug trials, testing, or regulatory approval of Rezulin.
- i) **Indemnification Agreements** entered into by or on behalf of Warner-Lambert to, or for the benefit of employees or personnel of the NIH, FDA, Congressmen, Senators, diabetes support, education, research, or advocacy organizations, physicians, or persons engaged in drug trials, testing, or regulatory approval of Rezulin.

23. All documents, correspondence, e-mails, communications created or received by  
**the following persons :**

Mark Bowden

Bob Brody

Diane Cairns

Peter Corr: President Pharmaceutical Research and Development, Parke-Davis

Stuart Domby: Parke-Davis Canadian Division, Head of International  
Development of Regulatory Affairs

Andrea Dunaif, M.D.: Senior Director Medical Research

Dr. Richard C. Eastman

Lisa Egbonu-Davis, M.D.: Head of Medical Liaison Group at Pfizer

F. Faich: Consultant

Eduardo Falstein, M.D.: Head of Standard Operating Procedures Group at Pfizer

Nancy Fitzsimmons: Marketing, Warner-Lambert

Dr. G. Alexander Fleming

Graham Frank: Head of International Development at Warner Lambert

Mahmoud Ghazzi, M.D.: Clinical Researcher at Parke-Davis

Ann Hards: Warner-Lambert Manager in Regulatory Affairs Department

Dr. Ivo Hynie: Gastroenterology, Hematology & Oncology Division, Health  
Protection Branch, Canada

Suzanne M. Jarose, B.S.: Clinical Research Associate, Clinical Research, Diabetic  
and Metabolic Disorders, Parke-Davis

Kenneth F. King, Senior VP Worldwide Regulatory Affairs, Warner-  
Lambert/Parke-Davis R & D

John Kirk: International Regulatory Affairs

Dr. Jeff Koup: Toxicologist

Marc Kustoff: Vice President Information Systems at Warner-Lambert

Tony Leachon: Vice President for Medical Affairs

Dr. Madre: Consultant

John Makowski: Clinical Research Associate, Diabetic and Metabolic Diseases

Irwin Martin: Senior Director of Regulatory Affairs

Dr. Janet McGill: Research

Dr. Ted McGuire: Toxicologist

Bill Merino: Head of U.S. Regulatory Affairs

Stephen Mock: Public Relations for Warner Lambert 1983-6/2000

Jerrold Olefsky: Chief University of California at San Diego

Alexandra Pearce, Ph.D.: Scientific Affairs Manager, CNS and Endocrinology

Bill Quick

Records Custodian of Rezulin Crisis File

Morris Renshaw: President

Rose Rogan, M.D.: Consultant

Byron Scott: Head of US Regulatory Affairs

William Sigmund, M.D.: Vice-President of Pfizer

Dr. Solomon Sobel



Howard Steinberg, M.D.

Mary Taylor: Senior Director Worldwide Regulatory Affairs, Warner-Lambert/Parke-Davis Research and Development

Robert Thompson, M.D.: Senior Director Medical Research

Silve Tomsic, M.D.: Medical Physician, Safety Group, Warner-Lambert

Dr. Paul Watkins: Consultant

Howard Weisman: Marketing, Warner-Lambert

Randall Whitcomb: Vice President Global Project Management at Pfizer Global Research and Development

J.Wright Witcher: Vice President of Marketing Warner Lambert

Dr. Robert Zerbe: Warner-Lambert Senior vice President of Worldwide Clinical Research

24. All proposed and utilized **package inserts and labeling** for Rezulin, including but not limited to: documentation, memoranda, drafts, emails and correspondence prepared by Warner-Lambert, its employees, or independent contractors relating to the package labeling, package insert labeling, and PDR information, labeling and warnings for Rezulin at any time.

25. All financial projections prepared by any person or entity at any time wherein Warner-Lambert projected or considered the potential or actual market share of **Avandia** or **Actos**.

26. All documentation, studies, memoranda or correspondence, prepared by any person or entity at any time, wherein Warner-Lambert considered, commented upon, or discussed the potential or actual liver toxicity or cardiac toxicity of **Actos** or **Avandia**.

27. All "Due Diligence" documents received or prepared by you, or prepared by third parties at your request relating to Pfizer's acquisition of Warner-Lambert, Parke-Davis.